ORIGINAL RESEARCH PAPER | Medical Science | Volume : 6 | Issue : 9 | September 2016 | ISSN - 2249-555X | IF : 3.919 | IC Value : 74.50

A Comparative Study of Post Operative Analgesia After Spinal Nalbuphine with Bupivacaine and Spinal Bupivacaine for Lower Limb Surgeries

KEYWORDS: Spinal anaesthesia, Nalbuphine, Hyperbaric Bupivacaine, Post-operative analgesia.

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ABSTRACT ***AIM:*** *The purpose of our study was to establish the effectiveness of intrathecal nalbuphine as an adjuvant and also the efficacy of nalbuphine for post-operative analgesia and its side effects if any.*

MATERIAL AND METHODS: *60 patients of ASA grade I and II, age group of 20-60 years, scheduled for elective lower limb surgeries were chosen for this study, patients were randomised into two equal groups of 30 each, group N (Nalbuphine group) received 3 cc of hyperbaric bupivacaine 0.5% + 0.8cc injection nalbuphine (0.8mg) intrathecally, Group B(controlled group) received 3cc of hyperbaric bupivacaine 0.5% + 0.8 cc of injection normal saline intrathecally, assessment of motor and sensory blockade was done by bromage scale and pinprick method, pulse rate, B. P, respiratory rate and SPO2 were monitored.*

RESULTS: *The difference was in significant between two groups from onset of sensory and motor blockade but mean time of post-operative analgesia in nalbuphine group –(Group-N)was highly significant than control group (Group-B), no patient developed any side effects in our study.*

CONCLUSION: *Nalbuphine used as an adjuvant to hyperbaric bupivacaine provides better quality of blockade as compared to hyperbaric bupivacaine alone, it also prolongs the post-operative analgesia when used as an adjuvant to spinal bupivacaine in lower limb surgeries.*

INTRODUCTION:

Spinal anesthesia is the best anesthetic technique for lower limb surgeries as it is simple to perform, with fast onset of anaesthesia and complete muscle relaxation. Intrathecal opioids are synergistic with local anesthetics and intensify the sensory blockade. The first report on the use of intrathecal opioids (ITO) for acute pain treatment was in 1979 by Wang and colleagues. 1 Use of ITO as an adjuncts has a definite place in the present regional anesthesia practice. Various opioids have been used along with bupivacaine to prolong its effect, to improve the quality of analgesia and minimize the requirement of postoperative analgesics. Nalbuphine is a semisynthetic opioid with mixed mu antagonist and k agonist properties. 2,3 Previous studies have shown that epidural or intrathecal administration of nalbuphine produces a significant analgesia accompanied by minimal pruritus and respiratory depression. Lin et al. found that the addition of intrathecal nalbuphine 0.8 mg to hyperbaric tetracaine, compared with intrathecal morphine 0.8 mg for SAB, improved the quality of intraoperative and postoperative analgesia, with fewer side-effects. In this prospective, randomized, controlled study, we tried to establish the effectiveness of intrathecal nalbuphine 0.8 mg add to 3cc of hyperbaric bupivacaine 0.5% as an adjuvant to have prolonged pain relief with minimal side effects in patient under going lower limb surgeries under SAB.

MATERIALS AND METHODS:

The study was conducted at NHL Municipal Hospital, Ahmedabad and written informed consent was obtained from all patients, 60 patients, ASA I and II, aged 20-60 years, scheduled for elective lower limb surgeries, of duration less than 3h, under spinal anaesthesia, were included in the study. Exclusion criteria will be Patients with a history of adverse response to bupivacaine or nalbuphine, pregnant patients, patients receiving phenothiazine, other tranquilizers, hypnotics or other central nervous system depressants (including alcohol) or suffering from peripheral or central neurological, cardiac, respiratory, hepatic, renal disease or with body weight more than 100 kg or less than 40 kg and height less than 145 cm or more than 160 cm and patients having contraindication to SAB were excluded from study. Patients were randomly allocated in to two groups. Group N n= 30, They receive 3 ml of hyperbaric bupivacaine 0.5% + 0.8ml injection nalbuphine (0.8,mg) intrathecally, Group B(c=30) receive 3ml of hyperbaric bupivacaine 0.5% + 0.8 ml injection normal saline intrathecally. All the patients fasted for at least 6 to 8 h before the procedure. After securing intravenous (18G) access in dorsum of the left hand and attaching routine monitors, preloading with Ringer's lactate solution 15 ml/kg over 15 min was done. SAB was performed with 3.8 ml of the study drug injected in L3/4 or L4/5 intervertebral space, using a 25 gauge Quincke spinal needle, in the sitting position, maintaining aseptic precautions, according to the standard institutional protocol. Thereafter, patients were placed in the supine or lateral position for surgery. Intraoperative fluid replacements were given as necessary depending on the blood loss and hemodynamic parameters. Intraoperative hypotension and bradycardia was managed with crystalloids or colloids and atropine 0.5 mg, respectively. In case of any respiratory depression, oxygen through facemask at 2 l/min it's administered. Advanced equipment's and drugs

Volume : 6 | Issue : 9 | September 2016 | ISSN - 2249-555X | IF : 3.919 | IC Value : 74.50

for resuscitation, airway management and ventilation were kept ready. The onset of sensory blockade (time taken from the end of injection to loss of pin prick sensation at T8 dermatome) and complete motor blockade (Time taken from the end of injection to development of grade IV motor block, modified Bromage's criteria), highest level of sensory blockade, duration of sensory blockade (two-segment regression time from highest level of sensory blockade), duration of motor blockade (time required for motor blockade return to Bromage's grade I from the time of onset of motor blockade) and duration of effective analgesia (time from the intrathecal injection to the first analgesic requirement, visual analogue scale [VAS] score 3.5 or more) were recorded. The changes in pulse rate, systolic and diastolic blood pressure, oxygen saturation (SpO2) and respiratory rate were recorded at 0, 2, 5,10 and 15 min and then at 10-min intervals up to 200 min after SAB, or up to the end point of study. Any side-effects in the form of post-operative hypotension, bradycardia, respiratory depression (Judged by respiratory rate less than 10 or SpO2 <90%) nausea and vomiting (in presence of stable hemodynamic parameters) and pruritus were recorded. Those patients who did not develop sensory block up to T8 and Grade IV motor block were excluded from the study. Intensity of pain was assessed by VAS at 0, 10, 15, 30 and 60 min and then at 30-min intervals till 5 hours after injection or until the patient received a rescue analgesic. Patients reporting a VAS score 3.5 or more received rescue analgesics in the form of injection (Inj) Diclofenac 75 mg IM. Incidence of nausea, vomiting and pruritus was noted. Nausea and vomiting was treated with Inj Ondansetron 4 mg i.v. and pruritus with anti-histamines. Data were analyzed using Student's t-test A P value less than 0.05 was considered statistically significant.

DISCUSSION:

Subarachnoid block is a technique of choice for lower limb surgeries, since subarachnoid block with bupivacaine has postoperative analgesia for short period. Intrathecal opioids (ITO)Used as adjuncts are capable of producing analgesia of prolonged duration but allow early ambulation of patients because of their sympathetic and motor nerve - sparing activity, many adjuvants like buprenorphine, morphine, fentanyl, clonidine, and midazolam have been used in the past to prolong post-operative analgesia, but everyone has its own side effects.4 Nalbuphine is a synthetic opioid structurally related to oximorphone, it is a highly lipid soluble opioid with an agonist action at the k- opioid receptor and antagonist activity at the mu –opioid receptor. Nalbuphine given systemically has a reduced incidence of respiratory depression and has been used to antagonize the side-effects of spinal opiates. There are a few studies of neuraxial administration of nalbuphine that have shown to produce a significant analgesia accompanied by minimal pruritus and respiratory depression. Lin et al5 found that the addition of intrathecal nalbuphine 0.8 mg to hyperbaric tetracaine, compared with intrathecal morphine 0.8 mg for SAB, improved the quality of intraoperative and postoperative analgesia, with fewer side-effects. Fournier et al.6studied the analgesic effects of intrathecal morphine 160 mcg and nalbuphine 400 mcg in geriatric patients scheduled for elective total hip replacement under continuous spinal anesthesia, given in the postoperative period, in the recovery room, and concluded that administration of intrathecal nalbuphine resulted in a significantly faster onset of pain relief and shorter duration of analgesia than intrathecal morphine. In 2011 study by Tiwari and Tomar7 showed that nalbuphine hydrochloride (400µg) significantly prolongs the duration of sensory blockade and post-operative analgesia without any side effect or complication when introduced intrathecally along with hyperbaric bupivacaine. A similar study showed that two-segment regression time of sensory blockade and duration of effective analgesia was prolonged in patients receiving 0.4 mg and 0.8 mg nalbuphine (P<0.05), and the incidence of side-effects was significantly higher in the latter group (P<0.05). The authors concluded that nalbuphine used intrathecally was a useful adjuvant in SAB and, in a dose of 0.8 mg, prolonged postoperative analgesia without increased side-effects.8 In our study we have used bupivacine with nulbuphine as an adjuvant to see the duration pf analgesia in post operatively and any side effect, after subarachnoid block was given there was no significant difference between onset of sensory and motor block in the both the groups

RESULTS:

Both the groups were comparable in various demographic data like age, gender, weight and also regarding ASA class distribution (table 1). There was no significant difference found in various hemodynamic or vital parameters intra operatively between the two groups.

Table 1: Demographic data (mean±SD)

variable	GROUP N	GROUP B	P VALUE
Age (years)	40.12±14.09	46.90±15.87	0.086
Weight (kg)	58.22±9.67	59.17±6.92	0.637
Gender (M:F)	21:9	23:7	0.873
ASA grade (I:II)	23:7	17:13	0.17

However, there was significant difference (p-value < 0.001) between mean onset and complete sensory block in group N and group B. The mean onset and complete motor block in group N and group B also showed statistical significance (p-value<0.05). Group N showing a faster onset compared to group B in both the cases (table 2). The distribution of sensory level in both the groups was similar. The mean regression in sensory (taken as regression up to L1 level) and motor block in group N and group B showed statistical significance (p-value < 0.001). Similarly, mean duration of requirement of first rescue analgesia in group N and group B showed significant difference (p-value <0.001), thus highlighting the fact that group N had prolonged post operative analgesia (table 2). Group N showed a significantly higher median Ramsay sedation score than group B (p-value<0.001).

Table 2: Duration of sensory and motor block and first rescue analgesia (mean±SD)

Parameter	GROUP N	GROUP B	P VALUE
Onset of sensory block (minute)	1.42±0.58	3.04±1.03	< 0.001
Onset of motor block (minute)	3.42±1.01	4.44±1.46	0.003
Regression of sensory block (minute)	216.50±34.72	122.50±20.14	< 0.001
Regression of motor block (minute)	242.3±56.46	141.12±22.58	< 0.001
First rescue analgesia (minute)	298.1±51.02	161±16.67	< 0.001
Median ramsay sedation score	3	2	< 0.001

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Side effects observed in group N were nausea, vomiting and urinary retention each in one patient. Two patients in group B had nausea while two had urinary retention (table 3).

Table 3: Side effects

Side effects	GROUP N	GROUP B
nausea	1	2
vomiting	1	0
Urinary retention	1	2

CONCLUSION:

Intrathecal nalbuphine added to hyper baric bupivacaine provides better quality of block and prolongs the post-operative analgesia for almost 7 to 8 hours as compared to hyper baric bupivacaine alone, without any significant side effects for patients undergoing lower limb surgeries under subarachnoid block.

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